Final Minutes
Registration Review Workgroup
Pesticide Program Dialogue Committee
March 1, 2004 Meeting
Crystal Mall 2, Arlington VA

Participants

EPA:	Jay Ellenberger, Susan Lewis, Carol Stangel, Philip Ross, Tony Kish, TJ Wyatt, Teresa Downs, Carl Young (EPA Region 6), Vivian Prunier
PPDC Workgroup:	Cindy Baker, Steve Kellner, Therese Murtagh, Julie Spagnoli, Ray McAllister, Warren Stickle, Julie Spagnoli, Sue Crescenzi, and Eric Olsen
Public attendees:	Janine Rynczak, CPDA; Mary Beth Polley, Pesticide and Toxic Chemical News, Phil Zahodiakin, Pesticide Insider; Daniel Botts, Florida Fruit and Vegetable Association; Karen Warkentien, CSI; Jim Kunstman, PBI Gordon; Gina Valerie, American Pet Products Manufacturers Association (by teleconference); John Wargen, PRMA Canada (by teleconference)

Introduction. Jay Ellenberger described the agenda for the meeting.

Minutes of February 2, 2004 Meeting. The workgroup discussed the draft minutes and requested that the summary of the discussion of issues one and two be amended to show the workgroup's preferred options.

Issue One. *What action(s) initiates a pesticide registration review?* Before expending resources in a pesticide's registration review, the Agency would want to know whether registrants intend to support the pesticide and each of its uses. Other stakeholders might want to know this as well. The Agency is seeking advice on options for getting this type of information up-front in a way that is efficient for both the Agency and the public.

Ray McAllister presented a summary of his subgroup's discussion, as follows:

1. No application is needed to initiate a pesticide's registration review or to affirm intent.
2. The Agency should publish a general schedule of registration review chemicals along with approximate timeframes. Publication of this schedule should coincide with or shortly follow the issuance of the final rule on registration review procedures.
3. EPA should update the schedule annually to confirm the schedule for the following year. The notice could include information about the pesticide's regulatory history, uses, recent risk assessments and possibly a bibliography. In addition, the notice could list on-going

DCI's, on-going reviews and the registrants of record.

4. The notice should establish a cut-off date for a registration review. Any new data requirements established after this date or any issues that arise after this date would not be considered in the pesticide's registration review. They would be addressed in separate DCI or review actions.

The workgroup discussed who should participate at the beginning of a pesticide's registration review. For example, registrants of specialized uses of a pesticide – e.g., public health uses – need to be included in the early stages of review. The "technical" registrants may not be aware that the pesticide has specialized uses because these uses do not appear on the technical registrant's labels and may not be interested in supporting these uses. HHS may support public health uses that aren't supported by technical registrants, but the proponents of the registration of public health uses need time to arrange for this support. Purchasers of technical pesticide products, some formulators and perhaps some growers or users should be included in early discussions about which uses should be supported. There should be a way for stakeholders to notify the Agency that they want to participate.

The issue was raised whether full notification as described above is necessary for pesticides that clearly qualify for the "easy off-ramp." However, since this is the information that the Agency would use in judging whether a pesticide qualifies for the "easy-off" ramp, the public may as well have a chance to see it before the Agency makes this judgment.

Another issue raised by the workgroup was the experience of growers and other stakeholders that labels of end-use products do not correspond to labeling changes mandated in the RED or in agreements negotiated by technical registrants and the Agency. For example as late as 1997, there were atrazine labels that did not conform to changes made in 1989. It was suggested that the notice described above also include a listing of label changes that have gone into effect as a result of REDs, label improvement programs or new registration decisions.

Workgroup members raised the possibility that the notification described above include a listing of incident or adverse effects data and a listing of new data requirements or changes in risks assessment methods that have occurred since the last evaluation of the pesticide.

To summarize the workgroup's position on issue one:

a) Publish long-term schedule.

b) A notice published closer to the registratin review data would include information specific to each case. It would show what EPA would consider in its review, including adverse effects information.

c) The notice would designate an Agency contact so that stakeholders can notify the Agency of their need to participate in the registration review.

Issue Two. *Early submission of test data and other information to support a pesticide's registration review.* The Agency wants to receive pertinent information early in the registration review process in order to avoid redoing its risk assessments. Such rework delays completion of the pesticide's review and ties up scarce resources.

Cindy Baker summarized the discussion of her subgroup as follows:

1) Stakeholders need a schedule.
2) Registrants need clearly articulated guidelines – what are the requirements at the time of a registration review?
3) Registrants will submit pertinent data if they have it.
4) Other stakeholders should know what the Agency's concerns are and how the Agency will use the stakeholders' information. This would guide stakeholders' selection and presentation of non-guideline data.

The Agency could provide guidance on how key risk assessment methods have changed over the years. This information would enable stakeholders to estimate whether a pesticide's risk assessment will need to be revised.

Registrants pointed out that it is burdensome to sort through voluminous old records to see if anything has been overlooked. It would help if the Agency could be more specific about the information that it is looking for.

Growers could contribute information on use and usage, and maybe regional information relating to worker exposures. But there isn't any structure for conducting studies or structuring the information.

Susan Lewis mentioned that worker groups may have information on the practicality of worker protection measures and perhaps on unreported incidents.

USDA could work with growers to develop timelines for use – a format for this information was developed during the reregistration program. However, USDA needs to know which pesticides are of interest several years in advance of the pesticide's registration review. EPA might not be able to provide useful guidance that far in advance.

The workgroup found that option 2 – in which EPA issues a DCI for "all relevant information" – is too broad. A DCI should be for a specific item. The Agency needs to define the scope of information that it expects from stakeholders.

Issue Five. *What is a registration review decision?* In a pesticide's registration review, the Agency would determine whether a pesticide meets the requirements for registration under FIFRA section 3(c)(5). Additionally, FIFRA section 3(g)(2)(A) stipulates that EPA shall use its authority under FIFRA section 3(c)(2)(B) to require submission of data when such data are

necessary for registration review.

The workgroup discussed a scenario where the Agency's evaluation showed that a pesticide did not meet the requirements of FIFRA 3(c)(5) and wondered when registration review ended and Special Review began.

Phil Ross of OGC explained that there were at least two possible outcomes when a registration review showed that the pesticide does not meet FIFRA section 3(c)(5). The Agency could issue a notice of intent of cancel (NOIC) under FIFRA section 6, or it could initiate a Special Review.

The Workgroup then discussed whether a pesticide's registration review could be deemed complete if the Agency's evaluation showed that additional data are needed to complete a risk assessment. EPA reiterated that if the Agency cannot make a risk finding, it cannot complete the registration review. EPA offered to provide the workgroup with legislative history to support this interpretation of the FIFRA(3)(g) requirement to conduct periodic reviews.

Sue Crescenzi, who presented the workgroup's findings on issue five, agreed that interim registration review evaluations could occur when the Agency finds that more data are needed to complete a risk assessment.

Ray McAllister expressed concern that if completion of a pesticide's registration review were deferred until submission of data needed to complete a risk assessment, the registration review would never be completed. By the time the Agency received and evaluated the new data, it would have found another issue that would prevent it from making a FIFRA(3)(c)(5) decision. He advocated that registration review be deemed complete when the Agency issued DCI's to fill data gaps that were identified in the registration review.

Eric Olson expressed concern that a pesticide's registration review might not be completed when there is a long-standing, unresolved Special Review. He advocated that the Agency use Registration Review to complete its assessment of the risks being examined in the Special Review.

EPA acknowledged that in cases with difficult issues, a pesticide's registration review could take years to complete.

Nonetheless, a registration review could be deemed "complete" in situations where the Agency has required data to confirm a risk assessment. This could occur when the Agency used worst case assumptions because data are not available to refine the risk assessment. In this case the data would confirm that actual risk is no worse than "worst case."

Economic impacts.

TJ Wyatt of BEAD summarized the paper that had been provided to workgroup members. He emphasized that the costs and benefits will vary depending on the options selected to resolve issues 1, 2 or 5. He suggested that the workgroup focus on the flow chart when developing their input on the costs and benefits of registration review.

Preparation for PPDC Meeting

The Workgroup will present recommendations on issues 1, 2 and 5 at the PPDC meeting in May. No date has been set for this meeting yet. Draft position papers will be distributed to workgroup members by April 1.

Next Workgroup Meetings. April 14 or 15th is the target date for the next workgroup meeting, followed by a final meeting the day before the PPDC meeting.

Action Items:

1. EPA will provide workgroup with a copy of the legislative history for FIFRA 3(g).

2. Ray McAllister will lead the write up of Issue One.

3. Cindy Baker will lead the write up of Issue Two.

4. Sue Crescenzi will lead the write up of Issue Five.

5. EPA will notify PPDC workgroup members of the dates and locations of the next workgroup meetings.